AMENDMENTS TO THE DRAWINGS

Please cancel Figure 6 as indicated in the Annotated Drawing Sheet submitted herewith.

REMARKS

Cancelation of Figure 6

The Applicants hereby repeat their request that Figure 6 be deleted from the drawings. This figure had been canceled during the international phase as specifically pointed out to the United States Patent and Trademark Office in a communication mailed January 10, 2007. In addition, an Application Data Sheet was filed on November 11, 2007, suggesting that Figure 3 accompany the abstract for publication. Applicant respectfully requests that, when a patent is granted on the present application, that such patent be published with Figure 3 on the face page.

Disposition of the Claims

Claims 32, 33 and 38-48 are presently pending. Amendments to Claim 1 are discussed below. Claim 1 is also amended by including the limitation of former Claim 40, which is now canceled. Claim 41 is amended to be consistent with amended Claim 32. No new matter has been added herewith.

The following addresses the substance of the Office Action.

Anticipation

Claims 32, 33, 38-41 and 48 were rejected under 35 U.S.C. § 102(b) as being anticipated by Martin (U.S. Patent No. 2,498,374).

The innovative features of the present invention include: (i) performing the method as an animal is dried off, and (ii) retaining a device in a teat streak canal. To emphasize the first aspect, Claim 32 is amended to recite "A method of reducing the chances of infection in an animal's udder during cessation of regular milking or involution comprising: inserting a device into an orifice of a teat of the udder and into a teat streak canal following cessation of regular milking or during involution..." The foregoing language emphasizes the timing of when the device is inserted. The term "involution" refers to the drying off period and is accompanied by shriveling of the mammary glands following cessation of regular milking. The time period "following cessation of regular milking" relates to the period when the cow is being dried off and will not be milked again for a prolonged period of time. This phrase does not refer to the end of a regular milking session, when the cow would be milked again on the same or next day. This is an

important distinction that helps to clarify that the present invention prevents development of infection during the drying off period. In contrast the Martin citation treats infections or removes blockages from the udder during the milking season (i.e., during the lactating phase while the animal is being regularly milked). Referring to column 2, lines 6-9 of Martin, the goal of the Martin method is:

> "so that the animal may be returned to the production line much more quickly than in cases where the old costly surgical treatment was employed."

Martin states at column 3, lines 62-69:

> "It is advisable, in an abundance of caution, prior to insertion of the bougie, to express two or three squirts of milk from the teat to remove any foreign material that may have lodged in the streak canal and a drop or two of milk on the end of the bougie prior to insertion will act as a lubricant and facilitate the passage of the bougie through the streak canal."

Thus, it is clear that the method of Martin is performed during the regular milking season and not "following cessation of regular milking or during involution."

With regard to the second aspect, the Examiner has not appreciated that Martin positions his device in the "teat canal," a term that Martin used to refer to the structure now termed the "teat cistern." Referring to column 4, lines 13-19, Martin discloses:

> "After the cam end **8** is forced upwardly into the streak canal, the end of the teat may be squeezed, as shown in Figure 5, to cause pressure on cam surface **8** to force the bougie into the dotted line shown in Figure 5. The bougie will then remain in the milk <u>in the teat canal</u> and dissolve". (emphasis added).

Figure 5 shows that the bougie is moved upwardly into position in the teat canal (presently termed the teat cistern). This is indicated by dotted line (**7**) in Figure 5, wherein no portion of the device remains in the teat streak canal, which is the passageway designated as structure **15** in Martin and as structure **5** in Figure 1 of the present specification. As shown in Figure 5 of Martin, the teat end is squeezed together at position 12, because the device is not retained in the teat streak canal. Thus, the method of Martin does not retain a device <u>within a treat streak canal</u> as presently claimed.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed.Cir. 1986). "[A]nticipation requires that all of the elements and limitations of the claim

are found within a single prior art reference." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991). Since the method of Martin is not performed following cessation of regular milking or during involution, and the method of Martin does not retain a device within a treat streak canal, Claim 32 and dependent claims thereof are not anticipated by Martin. Accordingly, the Applicant respectfully requests that the rejection under 35 U.S.C. § 102(b) be withdrawn.

Obviousness

There is no teaching in the prior art of the purpose and timing of inserting a device into an animal's teat streak canal as presently claimed. As outlined above, the time of implementation is important. Sometimes, dry period subclinical mastitis infections occur in the udder and these can be carried on to manifest themselves as clinical mastitis at calving or during the next lactation. For example, *Streptococcus uberis* is a type of bacteria that commonly infects dry udders and subsequently appears as clinical mastitis at calving time. The Applicant has found that, performing the presently claimed method following cessation of regular milking or during involution, protects the udder from new infections during the high-risk dry period, especially immediately after drying off. The issue of timing, and when the present invention is performed is not taught nor suggested by the prior art. As a result it would be impossible for the skilled person to combine the documents to reach the presently claimed invention. Accordingly the claimed invention involves an inventive step over the citations. The Applicant comments below on each of the Examiner's combinations of prior art.

Martin in view of Gordhamer

Claims 43-45 and 47 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Martin (*supra*) in view of Gordhamer (U.S. Patent No. 3,821,956). The Examiner acknowledged that Martin fails to specifically disclose that the retaining is enhanced by one or more surface features of the device. Thus, Gordhamer was cited as teaching a device, wherein retention in a teat duct is enhanced by one or more surface features of the device. However, neither Martin nor Gordhamer disclose the features of: (1) inserting a device into an orifice of a teat of the udder and into a teat streak canal following cessation of regular milking or during involution, or (2) retaining a device within a treat streak canal as required by the presently claimed method. Based on the

combined teachings of the cited references, one of ordinary skill in the art would have had no reason to develop the presently claimed methods. Accordingly, the claims are not *prima facie* obvious and the Applicant respectfully requests that the rejection be withdrawn.

Martin in view of Child

Claims 43 and 46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Martin (*supra*) in view of Child (U.S. Patent No. 4,385,633). Child was cited as teaching a device that has a plurality of protrusions. However, Child fails to fill the gap between Martin and the presently claimed methods which comprise: (1) inserting a device into an orifice of a teat of the udder and into a teat streak canal following cessation of regular milking or during involution, and (2) retaining a device within a treat streak canal. Thus, one of ordinary skill in the art would have had no reason to develop the presently claimed methods in view of Martin and Child. Accordingly, Claims 43 and 46 are not *prima facie* obvious and the Applicant respectfully requests that the rejection be withdrawn.

Smith in view of Martin

Claims 2 and 42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith (U.S. Patent No. 2,244,027) in view of Martin (*supra*). Referring to the first column at lines 3-9 of Smith, the reference discloses the use of a dilator that may be inserted into the teats of milk cows to relieve or prevent soreness and to assure ease of milking without pain and injury to the animal and with an unimpeded flow through the teat. Referring to the first column at lines22-31, such dilators are useful to treat conditions known as "spider and obstruction," which result in an obstruction that impedes or entirely prevents the extraction of milk. Such conditions may result from a trauma or mastitis. Thus, both Smith and Martin relate to treatment of animal teats during the milking season (i.e., while the animal is being regularly milked). Furthermore, Smith does not specify retaining the dilator within a treat streak canal. Accordingly, one of ordinary skill in the art would have had no reason to develop the presently claimed methods that comprise: (1) inserting a device into an orifice of a teat of the udder and into a teat streak canal following cessation of regular milking or during involution, and (2) retaining a device within a treat streak canal. As such, the claimed methods are not *prima facie* obvious and the Applicant respectfully requests that the rejection be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants' amendments to the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 28, 2011

By: /Raymond D. Smith/
Raymond D. Smith
Registration No. 55,634
Agent of Record
Customer No. 20995
(949) 760-0404

10789042
022811